

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant: Stephen J. Brown

Application No.: 10/826,107 Examiner: Rangrej, S.

Filed: April 16, 2004 Art Group: 3686

For: REMOTE HEALTH MONITORING AND MAINTENANCE SYSTEM

APPEAL BRIEF

Mail Stop - Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits the following Appeal Brief pursuant to 37 C.F.R. §41.37 for consideration by the Board of Patent Appeals and Interferences. Enclosed herewith is the charge \$540.00 to cover the cost of (i) filing the opening brief, as required by 37 C.F.R. §41.20(b)(2). Please charge any additional fees or credit any overpayment to Deposit Account Number 50-0541.

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I. REAL PARTY IN INTEREST

The real parties in interest are Health Hero Network, Inc., the assignee of record and a subsidiary of the Robert Bosch North America, and Abbott Diabetes Care, a subsidiary of Abbott Laboratories, Inc., a licensee of the application.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellant, Appellant's legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-60 are pending and remain rejected. The Appellant hereby appeals the rejection of claims 1-60.

IV. STATUS OF AMENDMENTS

Appellant is appealing a final Office Action issued by the Examiner on December 8, 2009. On February 1, 2010, Appellant filed a Response After Final. On March 11, 2010 the Examiner issued an Advisory Action. On April 2, 2010, Appellant filed a Notice of Appeal and a Pre-Appeal Brief Request for Review. On April 26, 2010, the Examiner issued a Notice of Panel Decision for Pre-Appeal Brief Review indicating that the case would proceed to the Board of Patent Appeals and Interferences.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In a first embodiment, represented by independent claim 1, the presently claimed invention provides a blood glucose monitoring system, comprising:

- a. a blood glucose monitor (e.g., block 16 in FIG. 1) for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals (e.g., 18 in FIG. 1) representative of said blood glucose level;
- b. a programmable microprocessor-based portable unit (e.g., block 12 in FIG. 1) that is separate from the blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video display (e.g., 28 in FIG. 1) for displaying information, said video display configured to display graphic and multi-line alphanumeric information (see paragraph [0077] in the specification), 2) a plurality of switches (e.g., 30, 32, 34, 36 and 38 in FIG. 1) operable for interactively controlling said programmable microprocessor-based portable unit and for manipulating the information displayed on said video display, and 3) a circuit (e.g., block 2076 in FIG. 15) coupled to said plurality of switches for generating video signals in response to the operation of the switches;
- c. a digital data storage medium (e.g., block 2080 in FIG. 15), the medium
 - A. readable by said programmable microprocessor-based portable unit (see paragraph [0121] in the specification); and
 - B. tangibly embodying therein a program of instructions (see paragraph [0075] in the specification) executable by said programmable microprocessor-based portable unit, said program of instructions including instructions for signal processing in response to signals (see paragraph [0110] in the specification) generated based upon said digitally encoded blood glucose

level signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage;

d. a signal interface (e.g., unit 110 in FIG. 11 and paragraph [0110] in the specification) connected in signal communication with said programmable microprocessor-based portable unit and said blood glucose monitor for coupling said digitally encoded blood glucose level signals supplied by said blood glucose monitor to said programmable microprocessor-based portable unit; and

e. signal processing means connected in signal communication with said signal interface for performing signal processing functions in accordance with said program of instructions (see paragraph [0075] in the specification).

In a second embodiment, represented by independent claim 17, the presently claimed invention provides a method of performing diabetes self-care with a system of integrated electronic devices, comprising:

powering a portable blood glucose monitor (e.g., block 16 in FIG. 1) with one or more batteries (see paragraph [0097] in the specification);

receiving an amount of blood (see paragraph [0101] in the specification) sufficient for a blood glucose monitor to run a blood glucose test sequence;

controlling the blood glucose test sequence (see paragraph [0101] in the specification);

computing a blood glucose level (see paragraph [0101] in the specification);

signal coupling the blood glucose monitor to a portable microprocessor-based electronic device (e.g., block 12 in FIG. 1) via a first data port (e.g., 14 in FIG. 1), wherein said portable microprocessor-based electronic device is separate from the blood glucose monitor and includes 1) a video display (e.g., 28 in FIG. 1) for displaying information, said video display configured to display graphic and multi-line alphanumeric information (see paragraph [0077] in the specification), 2) a plurality of switches (e.g., 30, 32, 34, 36 and 38 in FIG. 1) operable for interactively controlling said portable microprocessor-based electronic device and for manipulating the information displayed on said video display, and 3) a circuit (e.g., block 2076 in FIG. 15) coupled to said plurality of switches for generating video signals in response to the operation of the switches;

transmitting blood glucose test results (see paragraph [0080] in the specification) from said blood glucose monitor to said portable microprocessor-based electronic device;

running program instructions stored in a memory (see paragraphs [0075] and [0080] in the specification) of the portable microprocessor-based electronic device for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage; and

recording blood glucose test results and insulin dosage information in said memory of the portable microprocessor-based electronic device, said memory also containing programming for establishing a data protocol that allows digital data signal processing, and for performing said analysis of blood glucose (see paragraph [0124] in the specification).

In a third embodiment, represented by independent claim 28, the presently claimed invention provides a blood glucose monitoring system, comprising:

- a. a blood glucose monitor (e.g., block 16 in FIG. 1) for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals (e.g., paragraph [0086] in the specification) representative of said blood glucose level;
- b. a programmable microprocessor-based portable unit (e.g., element 12 in FIG. 1) that is separate from the blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video display (e.g., 28 in FIG. 1) for displaying information, said video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches (e.g., 30, 32, 34, 36 and 38 in FIG. 1) operable for interactively controlling said programmable microprocessor-based portable unit and for manipulating the information displayed on said video display, and 3) a circuit (e.g., block 2076 in FIG. 15) coupled to said plurality of switches for generating video signals in response to the operation of the switches;
- c. digital data storage media (see paragraph [0121] in the specification) tangibly embodying therein processor-executable program instructions for signal processing in response to signals based upon said digitally encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage and further for performing a test sequence to confirm that the system is operating properly;
- d. a signal interface (unit 110 in FIG. 11 and paragraph [0110] in the specification) connected in signal communication with said programmable microprocessor-based portable unit and said blood glucose monitor for coupling said digitally encoded health signals

supplied by said blood glucose monitor to said programmable microprocessor-based portable unit;
and

e. signal processing means connected in signal communication with said signal interface for performing signal processing functions in accordance with said program of instructions (see paragraph [0075] in the specification).

In a fourth embodiment, represented by independent claim 40, the presently claimed invention provides a system of interconnected devices for performing diabetes self-care, comprising:

(a) a blood glucose monitor (e.g., block 16 in FIG. 1), including:

- (i) a receptacle (see paragraph [0101] in the specification) for receiving an amount of blood sufficient for the monitor to run a blood glucose test sequence;
- (ii) processing circuitry (see paragraph [0102] in the specification) for controlling a blood glucose test sequence and computing a blood glucose level,
- (iii) a battery compartment (see paragraph [0097] in the specification) for holding a battery for powering the blood glucose monitor, and
- (iv) a first data port (e.g., 18 in FIG. 1) for signal coupling to another electronic device (see paragraph [0073] in the specification); and

(b) a portable microprocessor-based device (e.g., block 12 in FIG. 1) that is separate from the blood glucose monitor and signal coupled with the blood glucose monitor (see paragraph [0073] in the specification), including:

- (i) a second data port (e.g., 14 in FIG. 1) for signal coupling with the first data port and receiving blood glucose test results from said blood glucose monitor,
- (ii) a microprocessor (e.g., block 2076 in FIG. 15) that runs according to program instructions stored in a memory (see paragraph [0121] in the specification) for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage,
- (iii) a memory (e.g., block 2080 in FIG. 15) for recording the recorded blood glucose test results and insulin dosage information therein, and for containing programming for establishing a data protocol that allows digital data signal processing, and for performing analysis of blood glucose test results,
- (iv) a video display (e.g., 28 in FIG. 1) for displaying information, said video display configured to display graphic and multi-line alphanumeric information (see paragraph [0077] in the specification),
- (v) a plurality of switches (e.g., 30, 32, 34, 36 and 38 in FIG. 1) operable for interactively controlling said portable microprocessor-based device and for manipulating the information displayed on said video display, and
- (vi) a circuit (see paragraph [0122] in the specification) coupled to said plurality of switches for generating video signals in response to the operation of the switches.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first ground of rejection is whether claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54 and 59 are patentable under 35 U.S.C. §103(a) over DeMarzo¹ in view of Beckers.² Claim 60 was not included in the list of rejected claims on page 2 of the final Office Action.³ However, the omission of claim 60 appears to have been an oversight by the Examiner because claim 60 was argued on page 8 of the final Office Action as being unpatentable over DeMarzo in view of Beckers. Therefore, Appellant will proceed under the presumption that claim 60 is grouped and rejected along with claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54 and 59 as being unpatentable over DeMarzo in view of Beckers.

The second ground of rejection is whether claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-48 and 55-58 are patentable under 35 U.S.C. §103(a) over DeMarzo in view of Beckers and further in view of Reference U.⁴

¹ U.S. Patent No. 4,953,552

² U.S. Patent No. 5,019,974

³ mailed December 8, 2009

⁴ “Blood Glucose Monitors”, Portable Health Device (1988). Volume 17(9): pp. 253-271

VII. ARGUMENTS

A. 35 U.S.C. §103

This appeal is from two grounds of rejection: the first is set forth on page 2 of the final Office Action,⁵ where claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54 and 59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeMarzo in view of Beckers; the second is set forth on page 9 of the final Office Action, where claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-48 and 55-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U.

In rejecting claims under 35 U.S.C. §103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). “**All words in a claim must be considered** in judging the patentability of that claim against the prior art.”⁶ “Under §103, the scope and content of the prior art are to be determined; **differences between the prior art and the claims at issue** are to be ascertained; and **the level of ordinary skill in the pertinent art** resolved. Against this background the obviousness or nonobviousness of the subject matter is to be determined. Such secondary considerations as commercial success, long felt by unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter

⁵ Mailed December 8, 2009.

⁶ Manual of Patent Examining Procedure (M.P.E.P.), Eighth Edition, Rev. 7, July 2008, §2143.03 (emphasis added).

sought to be patented.”⁷ “To facilitate review, *this analysis should be made explicit*. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)(‘[R]ejections on obviousness grounds cannot be sustained by mere conclusory statement; instead, there must be *some articulated reasoning with some rational underpinning* to support the legal conclusion of obviousness’).”⁸

“If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of non-obviousness.”⁹ If the Examiner’s burden is met, the burden then shifts to the Appellant to overcome the *prima facie* case with argument and/or evidence. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments.¹⁰ As explained herein below, because the combination of DeMarzo, Beckers and Reference U does not teach each and every element of the claims, the claimed invention is patentable over the cited references and the rejections should be reversed.

1. The rejection of claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54, 59, and 60 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

As set forth on page 2 of the final Office Action, claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54 and 59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeMarzo in view of Beckers. Claim 60 was not included in the list of rejected claims on page 2 of the final

⁷ *KSR International Co. v. Teleflex Inc., et al.* 82 USPQ2d 1385 (2007) citing *Graham v. John Deere Co. Of Kansas City*, 383 U.S. 1 (1966).

⁸ *KSR International Co.*, 82 USPQ2d 1385 at 1396 (emphasis added).

⁹ M.P.E.P. §2142.

¹⁰ See *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Office Action.¹¹ However, the omission appears to have been an oversight by the Examiner because claim 60 was argued on page 8 of the final Office Action as being unpatentable over DeMarzo in view of Beckers. Therefore, the Appellant will proceed under the presumption that claim 60 is grouped and rejected along with claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54 and 59 as being unpatentable over DeMarzo in view of Beckers.

Claims 1-3, 8-11, 16-21, 26-29, 32-36, 39-44, 49-54, 59, and 60 do not stand or fall together. Rather, claim 1 (Group I), claim 8 (Group II), claim 17 (Group III), claim 28 (Group IV), claim 40 (Group V), claim 60 (Group VI), claims 2-3, 9-11 and 16 (Group VII), claims 18-21 and 26-27 (Group VIII), claims 29, 32-36 and 39 (Group IX), and claims 41-44 and 49-54 (Group X) are argued separately.

a. The rejection of claim 1 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claim 1 of the present invention provides a blood glucose monitoring system, comprising a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level, a portable microprocessor-based device that is separate from the blood glucose monitor and includes 1) a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the portable microprocessor-based device and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response

¹¹ mailed December 8, 2009

to the operation of the switches. The combination of DeMarzo and Beckers does not teach or suggest a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level and a programmable microprocessor-based portable unit that is separate from the blood glucose monitor, as presently claimed. As such, the presently claimed invention is fully patentable over the cited reference and the rejections should be reversed.

Specifically, the Examiner contends that DeMarzo teaches a blood glucose monitoring system, comprising a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level.¹² However, DeMarzo does not teach or suggest a blood glucose monitor that produces a digitally encoded blood glucose level signal, as presently claimed. At best, the device of DeMarzo uses a disposable adhesive patch having a needle type glucose sensor and a second electrode that produces electrical impulses that are measured by a microprocessor having leads for connection to the electrodes on the patch.¹³ The microprocessor of DeMarzo includes ammeter circuitry for receiving and measuring the electrical impulses from the sensor, and is programmed for calculating an average current value over a specified time period and for displaying that value upon an LCD readout.¹⁴ Since the electrodes of DeMarzo produce an analog signal (i.e., current associated with an electrical impulse for which ammeter circuitry is used for receiving and measuring), the electrodes

¹² See the middle of page 2 of the Final Office Action mailed 12-8-10.

¹³ Abstract and column 2, lines 5-28 of DeMarzo.

¹⁴ Column 2, lines 5-28 of DeMarzo.

of DeMarzo do not appear to be a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level, as presently claimed. A person of ordinary skill in the art would not view DeMarzo as having produced digitally encoded blood glucose level signals representative of a blood glucose level until after (i) the ammeter circuitry of DeMarzo receives and measures the analog electrical impulses from the electrodes and (ii) the microprocessor of DeMarzo calculates the average current value over the specified time period and displays a blood glucose value on the watchlike LCD readout. Even then, the digital numeric display of blood glucose levels by the LCD readout of DeMarzo does not provide digitally encoded blood glucose signals capable of being coupled to a separate programmable microprocessor based portable unit by a signal interface, as presently claimed. Therefore, if the microprocessor circuitry of DeMarzo is taken to correspond to the presently claimed microprocessor-based device, the electrodes of DeMarzo do not teach or suggest a blood glucose monitor for producing digitally encoded blood glucose level signals representative of the blood glucose level, as presently claimed.

Alternatively, if the entire device of DeMarzo is taken to be the blood glucose monitor as presently claimed and the recorder shown in FIG. 1 of Beckers is taken to be the microprocessor-based device as presently claimed, the combination of DeMarzo and Beckers still fails to teach a programmable microprocessor based portable unit that is separate from the blood glucose monitor, as presently claimed, because Beckers teaches a blood glucose monitor (i.e., a strip reader and a microprocessor based unit integrated in one single unit).¹⁵ There does not appear to be

¹⁵ See FIG. 1 of Beckers.

any teaching of a desirability of replacing the integrated strip reader with an external electrode based module such as DeMarzo discloses. The mere fact that a reference can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.¹⁶ DeMarzo and Beckers, alone or in combination, do not teach or suggest (i) a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level, (ii) a portable microprocessor-based device that is separate from the blood glucose monitor, and (iii) a signal interface connected in signal communication with the programmable microprocessor-based portable unit and the blood glucose monitor for coupling the digitally encoded blood glucose level signals supplied by the blood glucose monitor to the programmable microprocessor-based portable unit, as provided in claim 1.

As such, the rejection is not sustainable and should be reversed.

The Examiner also alleges that DeMarzo teaches a video display configured to display graphic and multi-line alphanumeric information.¹⁷ However, neither the device of DeMarzo, nor the device of Beckers has a **video display**, let alone a video display configured to display graphic and multi-line alphanumeric information, as presently claimed. DeMarzo is silent concerning a display configured to display multi-line alphanumeric information. At best, one of ordinary skill in the art would recognize the display of DeMarzo as being a single line seven-segment numeric display. DeMarzo shows a wristwatch like display that has numbers indicating the level of glucose

¹⁶ MPEP §2143.01(III).

¹⁷ See last six lines on page 2 of the final Office Action dated December 8, 2009.

in the blood and an indicator whether the level is increasing, decreasing, or steady.¹⁸ Therefore, DeMarzo does not teach or suggest a video display configured to display graphic and multi-line alphanumeric information, as presently claimed. Beckers does not cure the deficiencies of DeMarzo. At best, Beckers shows a display that appears to be capable of presenting only fixed symbols and a single line of numerals formed by a number of segments or lines.¹⁹ Beckers does not teach or suggest a video display configured to display graphic and multi-line alphanumeric information, as presently claimed.

Furthermore, the Examiner has not placed on the record a clear explanation of how the specific claim limitation in question is construed. The Examiner simply juxtaposed a copy of the amended claim limitation and a citation to DeMarzo reading “(DeMarzo: col. 5, 42-57).” The mere citation provided by the Examiner does not properly develop the record and issues to facilitate a reasonable review of the basis for the Examiner’s view that the cited portion of DeMarzo meets the specific language of the claim. Despite the lack of analysis by the Examiner to support the conclusion that the cited portion of DeMarzo meets the claim language, the combination of DeMarzo and Beckers does not teach or suggest all the elements of the presently claimed invention. Specifically, neither DeMarzo nor Beckers teach or suggest a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, as presently claimed. The LCD readout shown in FIG. 1 of DeMarzo only displays a single line of numeric data and an indicator. The LCD readout of DeMarzo is not described as

¹⁸ See element 28 of FIG. 1, column 2, lines 63-65, and column 5, lines 42-53 of DeMarzo.

¹⁹ See FIG. 2 of Beckers.

having a capability of displaying multiple lines of alphanumeric information. Therefore, DeMarzo and Beckers, alone or in combination, do not teach or suggest a portable microprocessor-based device that is separate from the blood glucose monitor and includes 1) a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the portable microprocessor-based device and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches, as provided in claim 1 and the rejection should be reversed.

Both the device of DeMarzo and the device of Beckers are stand alone blood glucose measuring devices. At best, the two devices would be viewed by those skilled in the field of the present invention as equivalent devices that could be exchanged for one another. The device of DeMarzo cannot be said to teach a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level AND a portable microprocessor-based device that is separate from the blood glucose monitor, as presently claimed. Similar to DeMarzo, the device of Beckers cannot be said to teach both a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level AND a portable microprocessor-based device that is separate from the blood glucose monitor, as presently claimed. FIG. 1 of Beckers shows a device, referred to in Beckers as a recorder. The recorder of Beckers is used by a patient to record blood glucose measurements using an integrated blood glucose test strip reader (see column 1, line 64 through column 2, line 37 of Beckers). In the device of Beckers, the blood glucose test

strip reader is integrated with the recorder.²⁰ In particular, Beckers shows the glucose strip reader 60 as part of the recorder.²¹ Therefore, the combination of DeMarzo and Beckers does not teach or suggest a microprocessor-based portable unit that is separate from a blood glucose monitor, as presently claimed. As such, the presently claimed invention is fully patentable over the cited references and the rejections should be reversed.

Furthermore, the motivation given by the Examiner for modifying Beckers “[to yield] predictable results because the level of ordinary skill in the art demonstrated by the references applied shows the ability to incorporate such data processing features into similar systems,”²² appears to be concerned with the abilities of the skilled artisan rather than the specific limitation recited in claim 1. No explanation is offered for why a person of ordinary skill in the art, with no knowledge of the present invention, would seek to combine the monitor of DeMarzo and the recorder of Beckers. The mere fact that a reference can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.²³ A statement that the claimed invention would have been within the ordinary skill of the art at the time the invention was made, because the references relied upon indicate that all aspects of the claimed invention were individually known in the art, is not sufficient to establish a *prima facie* case of

²⁰ see device in FIG. 1 of Beckers.

²¹ See element 60 in FIG. 1 of Beckers.

²² see bottom of page 4 of the Final Office Action dated December 8, 2009.

²³ see MPEP §2143.01(III).

obviousness without some objective reason to combine the teachings of the references.²⁴ Here, the Examiner appears to use material that is only taught by the Appellant, against its teacher, which is not proper.²⁵

Furthermore, “if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”²⁶ Also, “if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”²⁷ Breaking apart the recorder of Beckers, into a microprocessor portion and a glucose test strip reader portion, would prevent the automatic operation and storing of blood glucose measurements. Thus, severing the device of Beckers into a microprocessor portion and a glucose test strip reader portion would appear to make the resulting pieces unsatisfactory for the intended purpose and/or change the principle of operation. Similarly, separating the microprocessor of DeMarzo from the electrode patch would make the monitor of DeMarzo non-functional. Modifying the device of DeMarzo to connect to another separate device to send the blood glucose reading, rather than simply displaying

²⁴ see MPEP §2143.01(IV).

²⁵ *In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) (It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to “[use] that which the inventor taught against its teacher.” *W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency’s conclusion).

²⁶ MPEP §2143.01(VI).

²⁷ MPEP §2143.01(V).

the reading, would also change the principle of operation of the device of DeMarzo. The modification of DeMarzo would also make the monitor of DeMarzo unsatisfactory for its intended purpose, the continuous monitoring of blood glucose levels by a device which may be inconspicuously worn and causes minimal invasion into the body (see col. 1, lines 5-11 of DeMarzo). Therefore, there does not appear to be a suggestion or motivation for making a modification to either the monitor of DeMarzo or the integrated recorder of Beckers. Thus, for the reasons presented above, claim 1 is fully patentable over the cited references and the rejections should be reversed.

b. The rejection of claim 8 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claim 8 depends directly from claim 1 and, therefore, includes all the limitations of claim 1. Consequently, the arguments presented above in support of claim 1 are hereby incorporated by reference in support of claim 8. However, claim 8, recites a further limitation of “at least a component of the signal interface being connectable with a second device, other than the blood glucose monitor, in signal communication with the programmable microprocessor-based portable unit for coupling further signals supplied by the second device to the programmable microprocessor-based portable unit (see, for example, element 20 in FIG. 1). The combination of DeMarzo and Beckers does not teach or suggest a signal interface being connectable with a second device, other than the blood glucose monitor, in signal communication with the programmable microprocessor-based portable unit for coupling further signals supplied by the second device to the programmable microprocessor-based portable unit, as presently claimed.

Specifically, DeMarzo is silent concerning a second device. DeMarzo does not teach a signal interface being connectable with a second device, other than a blood glucose monitor. Beckers does not teach or suggest a signal interface connected in signal communication with the programmable microprocessor-based portable unit and the blood glucose monitor that is also connectable with a second device, other than the blood glucose monitor, as presently claimed. FIG. 3 of Beckers shows a sensor circuit input 58 that is used for blood glucose measurements with the blood glucose test strip reader 60 (see column 3, lines 60-64 and col. 6, lines 12-15 of Beckers). The blood glucose test strip reader connected to the microprocessor by the sensor circuit input 58 and an I2C bus (see elements 30, 42, and 58 in FIG. 3 of Beckers). Beckers does not teach or suggest the sensor circuit input 58 being connectable to a second device, other than the blood glucose test strip reader. Therefore, DeMarzo and Beckers does not teach or suggest a signal interface being connectable with a second device, other than the blood glucose monitor, in signal communication with the programmable microprocessor-based portable unit for coupling further signals supplied by the second device to the programmable microprocessor-based portable unit, as presently claimed. As such, the rejection of claim 8 is not sustainable and should be reversed.

Furthermore, the Examiner states that DeMarzo does not teach a signal interface being connectable with a second device, other than the blood glucose monitor, in signal communication with the programmable microprocessor-based portable unit for coupling further signals supplied by the second device to the programmable microprocessor-based portable unit, as presently claimed.. The Examiner relies on clause (a) of claim 12 of Beckers for curing the deficiency of DeMarzo. However, clause (a) of claim 12 is directed to a master computer. Beckers

states that the master computer connects to the recorder via an interface unit (column 9, lines 27-29 of Beckers). Beckers further states that the recorder connects to the interface unit by a separate serial interface 40 (column 3, lines 34-37 of Beckers). Since DeMarzo does not teach the limitations recited in claim 8 and Beckers uses two separate interfaces to connect the devices identified by the Examiner as corresponding to the presently claimed blood glucose monitor and the presently claimed second device, it follows that the combination of DeMarzo and Beckers does not teach or suggest each and every element of the presently pending claim 8. For the reasons presented above, claim 8 is independently patentable over the cited references and the rejection should be reversed.

Claim 8 has been grouped and argued separately by Appellant as identified by the separate subheading under which the above arguments appear. Appellant respectfully requests that the Board provide explicit analysis and reasoning concerning the patentability of claim and the reasons why the rejection is (or is not) reversed.²⁹

c. The rejection of claim 17 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claim 17 of the present invention provides a method of performing diabetes self-care with a system of integrated electronic devices. The method comprises steps of: (A) powering a portable blood glucose monitor with one or more batteries, (B) receiving an amount of blood sufficient for a blood glucose monitor to run a blood glucose test sequence, (C) controlling the blood glucose test sequence, (D) computing a blood glucose level, (E) signal coupling the blood glucose monitor to a portable microprocessor-based electronic device via a first data port, where the portable

²⁹ MPEP §1205 and §1205.02.

microprocessor-based electronic device is separate from the blood glucose monitor and includes 1) a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the portable microprocessor-based electronic device and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches, (F) transmitting blood glucose test results from the blood glucose monitor to the portable microprocessor-based electronic device, (G) running program instructions stored in a memory of the portable microprocessor-based electronic device for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage, and (H) recording blood glucose test results and insulin dosage information in the memory of the portable microprocessor-based electronic device, the memory also containing programming for establishing a data protocol that allows digital data signal processing, and for performing the analysis of blood glucose.

The limitations of claim 17 are similar to the limitations recited in claim 1. In particular, claim 17 recites steps of powering a portable blood glucose monitor with one or more batteries, receiving an amount of blood sufficient for a glucose monitor to run a blood glucose test sequence, controlling the blood glucose test sequence, and computing a blood glucose level. The above steps are similar to the recitation in claim 1 of a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals that are representative of the blood glucose level. Claim 17 further recites the step of signal coupling the blood glucose monitor to a portable microprocessor based electronic device by a first data port, wherein the

portable microprocessor based electronic device is separate from the blood glucose monitor and includes (1) a video display for displaying information, a video display configured to display graphic and multi-line alphanumeric information, (2) a plurality of switches operable for interactively controlling the portable microprocessor based electronic device and for manipulating the information displayed on the video display and (3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches. The performance of this step in claim 17 uses a microprocessor based portable unit having the same features as the programmable microprocessor based portable unit recited in claim 1.

Claim 17 further includes the step of running program instructions stored in a memory of the portable microprocessor based electronic device for performing analysis of a blood glucose test results signal processing of insulin dosage data and detect a need for a change in insulin dosage. The step of running program instructions stored in a memory in claim 17 is similar to the limitations in claim 1 concerning a digital data storage medium tangibly embodying a program of instructions executable by the programmable microprocessor based portable unit. Furthermore, the step involving signal coupling the blood glucose monitor to the portable microprocessor based electronic device via a first data port, recited in claim 17, is similar to the limitation in claim 1 of a signal interface connected in signal communication with the programmable microprocessor based portable unit and the blood glucose monitor for coupling the digitally encoded blood glucose level signals supplied by the blood glucose monitor to the programmable microprocessor based portable unit. Consequently, the arguments presented above in support of claim 1 are incorporated herein by reference in support of claim 17. For the reasons presented above that the combination of DeMarzo

and Beckers does not teach or suggest all the limitations recited in claim 1, DeMarzo and Beckers similarly does not teach or suggest all the limitations recited in claim 17. As such, claim 17 is fully patentable over the cited reference and the rejections should be reversed.

Claim 17 has been grouped and argued separately by Appellant as identified by the separate subheading under which the above arguments appear. Appellant respectfully requests that the Board provide explicit analysis and reasoning concerning the patentability of claim 17 and the reasons why the rejection is (or is not) reversed.³⁰

d. The rejection of claim 28 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claim 28 of the present invention provides a blood glucose monitoring system, comprising (a) a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level, (b) a programmable microprocessor-based portable unit that is separate from the blood glucose monitor, the programmable microprocessor-based portable unit including 1) a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the programmable microprocessor-based portable unit and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches, (c) digital data storage media tangibly embodying therein processor-executable program instructions for signal processing in response to signals based upon the digitally

³⁰ MPEP §1205 and §1205.02.

encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage and further for performing a test sequence to confirm that the system is operating properly, (d) a signal interface connected in signal communication with the programmable microprocessor-based portable unit and the blood glucose monitor for coupling the digitally encoded health signals supplied by the blood glucose monitor to the programmable microprocessor-based portable unit, and (e) signal processing means connected in signal communication with the signal interface for performing signal processing functions in accordance with the program of instructions.

Claim 28 includes limitations similar to limitations recited in claim 1. In particular, claim 28 recites a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level. This is similar to the recitation in claim 1 of a blood glucose monitor for monitoring a blood glucose level and for producing digitally encoded blood glucose level signals representative of the blood glucose level. Claim 28 further recites a programmable microprocessor-based portable unit that is separate from the blood glucose monitor, the programmable microprocessor-based portable unit including 1) a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, 2) a plurality of switches operable for interactively controlling the programmable microprocessor-based portable unit and for manipulating the information displayed on the video display, and 3) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches. The description of the programmable microprocessor-based portable unit in claim 28 is similar to limitations recited in claim 1. Claim

28 further includes a digital data storage media tangibly embodying therein processor-executable program instructions for signal processing in response to signals based upon the digitally encoded blood glucose signals and further for signal processing of insulin dosage data and detecting a need for a change in insulin dosage and further for performing a test sequence to confirm that the system is operating properly. The digital data storage media of claim 28 stores program instructions which may be processor-executable to detect a need for a change in insulin dosage similar to the digital data storage medium recited in claim 1. Claim 28 further recites a signal interface connected in signal communication with the programmable microprocessor-based portable unit and the blood glucose monitor for coupling the digitally encoded health signals supplied by the blood glucose monitor to the programmable microprocessor-based portable unit. The signal interface recited in claim 28 couples digitally encoded health signals from the blood glucose monitor to the microprocessor-based unit similar to the signal interface recited in claim 1. Consequently, the arguments presented above in support of claim 1 are incorporated herein by reference in support of claim 28. For the reasons presented above that the combination of DeMarzo and Beckers does not teach or suggest all of the limitations recited in claim 1, DeMarzo and Beckers similarly does not teach or suggest all the limitations recited in claim 28. As such, the presently claimed invention is fully patentable over the cited reference and the rejections should be reversed.

Furthermore, in addition to the limitations that are similar to limitations of claim 1, claim 28 recites the limitation that the digital data storage media, tangibly embodying therein processor-executable program instructions for signal processing in response to signals based upon the digitally encoded blood glucose signals and further for signal processing of insulin dosage data

and detecting a need for a change in insulin dosage, also embodies processor-executable program instructions for performing a test sequence to confirm that the system is operating properly. The Examiner fails to allege, let alone make the requisite factual findings and analysis required by Federal Circuit and Supreme Court precedent. In rejecting claims under 35 U.S.C. §103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). “*All words in a claim must be considered* in judging the patentability of that claim against the prior art.”³¹ “Under §103, the scope and content of the prior art are to be determined; *differences between the prior art and the claims at issue* are to be ascertained; and *the level of ordinary skill in the pertinent art* resolved. Against this background the obviousness or nonobviousness of the subject matter is to be determined. Such secondary considerations as commercial success, long felt by unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”³² “To facilitate review, *this analysis should be made explicit*. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)(‘[R]ejections on obviousness grounds cannot be sustained by mere conclusory statement; instead, there must be *some articulated reasoning with some rational underpinning* to support the legal conclusion of

³¹ Manual of Patent Examining Procedure (M.P.E.P.), Eighth Edition, Rev. 7, July 2008, §2143.03 (emphasis added).

³² *KSR International Co. v. Teleflex Inc., et al.* 82 USPQ2d 1385 (2007) citing *Graham v. John Deere Co. Of Kansas City*, 383 U.S. 1 (1966).

obviousness')."³² Despite the Examiner's lack of fact finding and analysis, DeMarzo and Beckers do not teach or suggest the digital data storage media tangibly embodying processor-executable program instructions for performing a test sequence to confirm the system is operating properly, as presently claimed. Since the Examiner has not produced a *prima facie* case, the Appellant is under no obligation to submit evidence of non-obviousness.³³ As such, claim 28 is independently patentable over the cited references and the rejection should be reversed.

Claim 28 has been grouped and argued separately by Appellant as identified by the separate subheading under which the above arguments appear. Appellant respectfully requests that the Board provide explicit analysis and reasoning concerning the patentability of claim 28 and the reasons why the rejection is (or is not) reversed.³⁴

e. The rejection of claim 40 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claim 40 of the present invention provides a system of interconnected devices for performing diabetes self-care, comprising (a) a blood glucose monitor, including (i) a receptacle for receiving an amount of blood sufficient for the monitor to run a blood glucose test sequence, (ii) processing circuitry for controlling a blood glucose test sequence and computing a blood glucose level, (iii) a battery compartment for holding a battery for powering the blood glucose monitor, and (iv) a first data port for signal coupling to another electronic device and (b) a portable

³² *KSR International Co.*, 82 USPQ2d 1385 at 1396 (emphasis added).

³³ M.P.E.P. §2142.

³⁴ MPEP §1205 and §1205.02.

microprocessor-based device that is separate from the blood glucose monitor and signal coupled with the blood glucose monitor, including (i) a second data port for signal coupling with the first data port and receiving blood glucose test results from the blood glucose monitor, (ii) a microprocessor that runs according to program instructions stored in a memory for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage, (iii) a memory for recording the recorded blood glucose test results and insulin dosage information therein, and for containing programming for establishing a data protocol that allows digital data signal processing, and for performing analysis of blood glucose test results, (iv) a video display for displaying information, the video display configured to display graphic and multi-line alphanumeric information, (v) a plurality of switches operable for interactively controlling the portable microprocessor-based device and for manipulating the information displayed on the video display, and (vi) a circuit coupled to the plurality of switches for generating video signals in response to the operation of the switches.

Claim 40 includes limitations similar to limitations recited in claim 1. In particular, claim 40 recites a blood glucose monitor, including (i) a receptacle for receiving an amount of blood sufficient for the monitor to run a blood glucose test sequence, (ii) processing circuitry for controlling a blood glucose test sequence and computing a blood glucose level, (iii) a battery compartment for holding a battery for powering the blood glucose monitor, and (iv) a first data port for signal coupling to another electronic device. The blood glucose monitor recited in claim 40 is similar to the blood glucose monitor for monitoring a blood glucose level as recited in claim 1. Claim 40 further recites a portable microprocessor-based device that is separate from the blood

glucose monitor and signal coupled with the blood glucose monitor. The microprocessor-based device recited in claim 40 includes elements that are similar to the elements of the microprocessor-based unit recited in claim 1. Claim 40 also includes program instructions stored in a memory for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage. Running program instructions stored in a memory to detect a need for a change in insulin dosage as recited in claim 40 is similar to the limitations in claim 1 concerning a digital data storage medium tangibly embodying a program of instructions executable by the programmable microprocessor-based portable unit and detecting a need for a change in insulin dosage. Consequently, the arguments presented above in support of claim 1 are incorporated herein by reference in support of claim 40. For the reasons presented above that the combination of DeMarzo and Beckers does not teach or suggest all of the limitations recited in claim 1, DeMarzo and Beckers similarly does not teach or suggest all the limitations recited in claim 40. As such, the presently claimed invention is fully patentable over the cited reference and the rejections should be reversed.

Claim 40 has been grouped and argued separately by Appellant as identified by the separate subheading under which the above arguments appear. Appellant respectfully requests that the Board provide explicit analysis and reasoning concerning the patentability of claim 40 and the reasons why the rejection is (or is not) reversed.³⁶

³⁶ MPEP §1205 and §1205.02.

f. The rejection of claim 60 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claim 60 depends directly from claim 1 and, therefore, include all the limitations of claim 1. Consequently, the arguments presented above in support of claim 1 are hereby incorporated by reference in support of claim 60. However, claim 60, recites a further limitation that the video display has a resolution sufficient to display at least six lines of alphanumeric information, as well as allowing graphical representation of statistical data (see, for example, elements 28 in FIG. 1 and paragraph [0077] of the specification). The combination of DeMarzo and Beckers does not teach or suggest a video display that has a resolution sufficient to display at least six lines of alphanumeric information, as well as allowing graphical representation of statistical data, as presently claimed. Specifically, DeMarzo discloses a wristwatch-like LCD readout 28 (see FIG. 1 of DeMarzo). The LCD readout 28 of DeMarzo displays a blood glucose level as a single line of numerals, accompanied by an indicator, e.g., upward pointing arrow 80, downward pointing arrow, or hyphen (see column 5, lines 42-57 of DeMarzo). DeMarzo does not teach or suggest that the video display has a resolution sufficient to display at least six lines of alphanumeric information, as well as allowing graphical representation of statistical data , as presently claimed.

Beckers also fails to teach or suggest the video display has a resolution sufficient to display at least six lines of alphanumeric information, as well as allowing graphical representation of statistical data, as presently claimed. FIG. 2 of Beckers shows an LCD readout that presents various symbols and a single line of numeric digits formed by various segments (see column 3, lines 1-20 of Beckers). Since neither DeMarzo nor Beckers teach or suggest LCD readouts capable of displaying at least six lines of alphanumeric information, it follows that the combination of DeMarzo

and Beckers does not teach or suggest the video display has a resolution sufficient to display at least six lines of alphanumeric information, as well as allowing graphical representation of statistical data, as presently claimed. Therefore, DeMarzo and Beckers does not teach or suggest each and every element of the claim 60. As such, claim 60 is independently patentable over the cited references and the rejection should be reversed.

Claim 60 has been grouped and argued separately by Appellant as identified by the separate subheading under which the above arguments appear. Appellant respectfully requests that the Board provide explicit analysis and reasoning concerning the patentability of claim 60 and the reasons why the rejection is (or is not) reversed.³⁷

g. The rejection of claims 2-3, 9-11 and 16 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claims 2-3, 9-11 and 16 depend, directly or indirectly, from claim 1 and, therefore, include all the limitations of claim 1. Consequently, the arguments presented above in support of claim 1 are hereby incorporated by reference in support of claims 2-3, 9-11 and 16. However, these claims recite additional limitations, e.g., that the programmable microprocessor-based portable unit further comprises an interactive interface (see, for example, paragraph [0112] of the specification and FIG. 11). The combination of DeMarzo and Beckers as a basis for rejecting claims 2, 3, 9-11 and 16 is not proper and the rejections should be reversed.

³⁷ MPEP §1205 and §1205.02.

Specifically, the modification of DeMarzo makes the device of DeMarzo unsatisfactory for the intended purpose and, therefore, there is no suggestion or motivation for the combination (MPEP §2143.01(V)). In particular, DeMarzo states that the invention of DeMarzo relates specifically to a miniaturized blood glucose monitoring system which **may be inconspicuously worn by a patient and provides a relatively continuous monitoring of the blood glucose level** while causing a minimal invasion into the body (column 1, lines 5-11 of DeMarzo). Modification of DeMarzo with the handheld recorder or teststrip reader of Beckers would defeat the goal of a device that can be inconspicuously worn and provides continuous monitoring of blood glucose levels. Thus, the modification of DeMarzo with the features of Beckers (e.g., discrete blood glucose measurements based in highly invasive blood samples) would render the device of DeMarzo unsatisfactory for its intended purpose. Therefore, there is no suggestion or motivation for the proposed combination. For the reasons presented above, claims 2, 3, 9-11 and 16 are independently patentable over the cited references and the rejections should be reversed.

h. The rejection of claims 18-21 and 26-27 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claims 18-21 and 26-27 depend, directly or indirectly, from claim 17 and, therefore, include all the limitations of claim 17. Consequently, the arguments presented above in support of claim 17 are hereby incorporated by reference in support of claims 18-21 and 26-27. However, these claims, in particular claim 20, recite a further limitation that the portable, microprocessor-based

electronic device comprises a palm-top computer (see, for example, paragraph [0035] of the specification and element 12 in FIG. 1). The combination of DeMarzo and Beckers does not teach or suggest a portable, microprocessor-based electronic device comprising a palm-top computer, as presently claimed. Furthermore, the combination of DeMarzo and Beckers as a basis for rejecting claims 18-21 and 26-27 is not proper and the rejections should be reversed.

Specifically, the modification of DeMarzo makes the device of DeMarzo unsatisfactory for the intended purpose and, therefore, there is no suggestion or motivation for the combination (MPEP §2143.01(V)). In particular, DeMarzo states that the invention of DeMarzo relates specifically to a miniaturized blood glucose monitoring system which **may be inconspicuously worn by a patient and provides a relatively continuous monitoring of the blood glucose level** while causing a minimal invasion into the body (column 1, lines 5-11 of DeMarzo). Modification of DeMarzo with the handheld recorder or test strip reader of Beckers would defeat the goal of a device that can be inconspicuously worn and provides continuous monitoring of blood glucose levels. Thus, the modification of DeMarzo with the features of Beckers (e.g., discrete blood glucose measurements based in highly invasive blood samples) would render the device of DeMarzo unsatisfactory for its intended purpose. Therefore, there is no suggestion or motivation for the proposed combination. For the reasons presented above, claims 18-21 and 26-27 are independently patentable over the cited references and the rejections should be reversed.

i. **The rejection of claims 29, 32-36 and 39 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.**

Claims 29, 32-36 and 39 depend, directly or indirectly, from claim 28 and, therefore, include all the limitations of claim 28. Consequently, the arguments presented above in support of claim 28 are hereby incorporated by reference in support of claims 29, 32-36 and 39. However, these claims, in particular claim 30, recite additional limitations that the program of instructions including instructions further for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip. The combination of DeMarzo and Beckers does not teach or suggest a program of instructions including instructions further for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip, as presently claimed.

Specifically, the modification of DeMarzo makes the device of DeMarzo unsatisfactory for the intended purpose and, therefore, there is no suggestion or motivation for the combination (MPEP §2143.01(V)). In particular, DeMarzo states that the invention of DeMarzo relates specifically to a miniaturized blood glucose monitoring system which **may be inconspicuously worn by a patient and provides a relatively continuous monitoring of the blood glucose level** while causing a minimal invasion into the body (column 1, lines 5-11 of DeMarzo). Modification of DeMarzo with the handheld recorder or teststrip reader of Beckers would defeat the goal of a device that can be inconspicuously worn and provides continuous monitoring of blood glucose levels. Thus, the modification of DeMarzo with the features of Beckers (e.g., discrete blood

glucose measurements based in highly invasive blood samples) would render the device of DeMarzo unsatisfactory for its intended purpose. Therefore, there is no suggestion or motivation for the proposed combination. For the reasons presented above, claims 29, 32-36 and 39 are independently patentable over the cited references and the rejections should be reversed.

Claims 29, 32-36 and 39 have been grouped and argued separately by Appellant as identified by the separate subheading under which the above arguments appear. Appellant respectfully requests that the Board provide explicit analysis and reasoning concerning the patentability of claims 29, 32-36 and 39 and the reasons why the rejections are (or are not) reversed.³⁷

j. The rejection of claims 41-44 and 49-54 as being unpatentable over DeMarzo in view of Beckers is not sustainable and should be reversed.

Claims 41-44 and 49-54 depend, directly or indirectly, from claim 40 and, therefore, include all the limitations of claim 40. Consequently, the arguments presented above in support of claim 40 are hereby incorporated by reference in support of claims 41-44 and 49-54. However, these claims, in particular claim 42, recite additional limitations that the blood glucose monitor further comprises a display for displaying the blood glucose level (see, for example, element 28 in FIG. 1). The combination of DeMarzo and Beckers does not teach or suggest a portable, microprocessor-based electronic device comprising a palm-top computer, as presently claimed.

³⁷ MPEP §1205 and §1205.02.

Specifically, the modification of DeMarzo makes the device of DeMarzo unsatisfactory for the intended purpose and, therefore, there is no suggestion or motivation for the combination (MPEP §2143.01(V)). In particular, DeMarzo states that the invention of DeMarzo relates specifically to a miniaturized blood glucose monitoring system which **may be inconspicuously worn by a patient and provides a relatively continuous monitoring of the blood glucose level** while causing a minimal invasion into the body (column 1, lines 5-11 of DeMarzo). Modification of DeMarzo with the handheld recorder or teststrip reader of Beckers would defeat the goal of a device that can be inconspicuously worn and provides continuous monitoring of blood glucose levels. Thus, the modification of DeMarzo with the features of Beckers (e.g., discrete blood glucose measurements based in highly invasive blood samples) would render the device of DeMarzo unsatisfactory for its intended purpose. Therefore, there is no suggestion or motivation for the proposed combination. For the reasons presented above, claims 41-44 and 49-54 are independently patentable over the cited references and the rejections should be reversed.

2. The rejection of claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-48 and 55-58 as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U is not sustainable and should be reversed.

As set forth on page 9 of the final Office Action,³⁸ claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-48 and 55-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U. Claims 4-7, 12-15, 22-25, 30-31, 37-38, 45-

³⁸ mailed December 8, 2009

48 and 55-58 do not stand or fall together. Rather, claims 4-7 and 12-15 (Group I), claims 22-25 (Group II), claims 30-31 and 37-38 (Group III) and claims 45-48 and 55-58 (Group IV) are argued separately.

- a. **The rejection of claims 4-7 and 12-15 as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U is not sustainable and should be reversed.**

Claims 4-7 and 12-15 depend, directly or indirectly, from claim 1 and, therefore, include all the limitations of claim 1. Consequently, the arguments presented above in support of claim 1 are hereby incorporated by reference in support of claims 4-7 and 12-15. However, these claims, in particular claim 7, recite a further limitation that the program of instructions further including instructions for performing a test sequence to confirm that the system is operating properly (see, for example, paragraph [0084] of the specification). The combination of DeMarzo, Beckers, and Reference U does not teach or suggest a program of instructions further including instructions for performing a test sequence to confirm that the system is operating properly, as presently claimed.

The addition of Reference U to the combination of DeMarzo and Beckers does not cure the deficiencies of DeMarzo and Beckers. Specifically, Reference U is an article evaluating eight blood glucose monitors, from six manufacturers, that use strips for self-monitoring of blood glucose levels. Reference U appears to be cumulative to Beckers. Reference U appears silent regarding either (a) a video display for displaying information, where the video display is configured to display graphic and multi-line alphanumeric information, as recited in claim 1, or (b) a digital data

storage medium tangibly embodying therein a program of instructions executable by the programmable microprocessor-based portable unit, where the program of instructions includes any of (i) instructions for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip, (ii) instructions for monitoring whether the test strip is properly inserted into the monitor, or (iii) instructions for performing a test sequence to confirm that the system is operating properly, as recited, *inter alia*, in claims 4-7 and 12-15. Therefore, even with the addition of Reference U to the combination of DeMarzo and Beckers, the cited references do not teach or suggest each and every element recited in claims 4-7 and 12-15. As such, the rejections of claims 4-7 and 12-15 are not sustainable and should be reversed.

Thus, for the reasons presented above, claims 4-7 and 12-15 are independently patentable over the cited references and the rejections should be reversed.

b. The rejection of claims 22-25 as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U is not sustainable and should be reversed.

Claims 22-25 depend, directly or indirectly, from claim 17 and, therefore, include all the limitations of claim 17. Consequently, the arguments presented above in support of claim 17 are hereby incorporated by reference in support of claims 22-25. However, these claims, in particular claim 23, recite a further limitation that the controlling further comprises monitoring whether the test strip is properly inserted into the monitor. The combination of DeMarzo, Beckers, and Reference U does not teach or suggest that the controlling further comprises monitoring whether the test strip

is properly inserted into the monitor, as presently claimed.

The addition of Reference U to the combination of DeMarzo and Beckers does not cure the deficiencies of DeMarzo and Beckers. Specifically, Reference U is an article evaluating eight blood glucose monitors, from six manufacturers, that use strips for self-monitoring of blood glucose levels. Reference U appears to be cumulative to Beckers. Reference U appears silent regarding either (a) a video display for displaying information, where the video display is configured to display graphic and multi-line alphanumeric information, as recited in claim 17, or (b) controlling the blood glucose test sequence comprising any of (i) monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip, (ii) monitoring whether the test strip is properly inserted into the monitor, or (iii) performing a test sequence to confirm that the system is operating properly, as recited, *inter alia*, in claims 22-25. Therefore, even with the addition of Reference U to the combination of DeMarzo and Beckers, the cited references do not teach or suggest each and every element recited in claims 22-25. As such, the rejections of claims 22-25 are not sustainable and should be reversed.

Thus, for the reasons presented above, claims 22-25 are independently patentable over the cited references and the rejections should be reversed.

c. **The rejection of claims 30-31 and 37-38 as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U is not sustainable and should be reversed.**

Claims 30-31 and 37-38 depend, directly or indirectly, from claim 28 and, therefore, include all the limitations of claim 28. Consequently, the arguments presented above in support of claim 28 are hereby incorporated by reference in support of claims 30-31 and 37-38. However, these claims, in particular claim 30, recite a further limitation that the program of instructions includes instructions further for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip. The combination of DeMarzo, Beckers, and Reference U does not teach or suggest that the program of instructions includes instructions further for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip, as presently claimed.

The addition of Reference U to the combination of DeMarzo and Beckers does not cure the deficiencies of DeMarzo and Beckers. Specifically, Reference U is an article evaluating eight blood glucose monitors, from six manufacturers, that use strips for self-monitoring of blood glucose levels. Reference U appears to be cumulative to Beckers. Reference U appears silent regarding either (a) a video display for displaying information, where the video display is configured to display graphic and multi-line alphanumeric information, as recited in claim 28, or (b) digital data storage media tangibly embodying therein a program of instructions executable by the programmable microprocessor-based portable unit, where the program of instructions includes any of (i) instructions for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip or (ii) instructions for monitoring whether the test strip is

properly inserted into the monitor, as recited, *inter alia*, in claims 30, 31, 37 and 38. Therefore, even with the addition of Reference U to the combination of DeMarzo and Beckers, the cited references do not teach or suggest each and every element recited in claims 30, 31, 37 and 38. As such, the rejections of claims 30, 31, 37 and 38 are not sustainable and should be reversed.

Thus, for the reasons presented above, claims 30-31 and 37-38 are independently patentable over the cited references and the rejections should be reversed.

d. The rejection of claims 45-48 and 55-58 as being unpatentable over DeMarzo in view of Beckers and further in view of Reference U is not sustainable and should be reversed.

Claims 45-48 and 55-58 depend, directly or indirectly, from claim 40 and, therefore, include all the limitations of claim 40. Consequently, the arguments presented above in support of claim 40 are hereby incorporated by reference in support of claims 45-48 and 55-58. However, these claims, in particular claim 45, recite a further limitation that the program of instructions includes instructions for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip. The combination of DeMarzo, Beckers, and Reference U does not teach or suggest that the program of instructions includes instructions further for monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip, as presently claimed.

The addition of Reference U to the combination of DeMarzo and Beckers does not cure the deficiencies of DeMarzo and Beckers. Specifically, Reference U is an article evaluating

eight blood glucose monitors, from six manufacturers, that use strips for self-monitoring of blood glucose levels. Reference U appears to be cumulative to Beckers. Reference U appears silent regarding either (a) a video display for displaying information, where the video display is configured to display graphic and multi-line alphanumeric information, as recited in claim 40, or (b) a memory for containing programming, where the program of instructions includes instructions for (i) monitoring whether a sufficient amount of blood has been applied to the reagent impregnated portion of the test strip, (ii) monitoring whether the test strip is properly inserted into the monitor, or (iii) performing a test sequence to confirm that the system is operating properly, as recited, *inter alia*, in claims 45-48 and 55-58. Therefore, even with the addition of Reference U to the combination of DeMarzo and Beckers, the cited references do not teach or suggest each and every element recited in claims 45-48 and 55-58. As such, the rejections of claims 45-48 and 55-58 are not sustainable and should be reversed.

Thus, for the reasons presented above, claims 45-48 and 55-58 are independently patentable over the cited references and the rejections should be reversed.

B. CONCLUSION

None of the cited references teach or suggest a video display for displaying information, where the video display is configured to display graphic and multi-line alphanumeric information, as provided in claims 1-60. Hence, the Examiner has clearly erred with respect to the patentability of the claimed invention. It is respectfully requested that the Board overturn the Examiner's rejection of all pending claims, and hold that the claims are not rendered obvious by the cited reference. However, should the Board find the arguments herein in support of independent claims 1, 17, 28 and/or 40 unpersuasive, the Board is respectfully requested to carefully consider the arguments set forth above in support of each of the independently patentable groups.

Respectfully submitted,
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Dated: June 2, 2010

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VIII. CLAIM APPENDIX

The claims of the present application which are involved in this appeal are as follows:

- 1 1. A blood glucose monitoring system, comprising:
 - 2 a. a blood glucose monitor for monitoring a blood glucose level and for
 - 3 producing digitally encoded blood glucose level signals representative of said blood glucose level;
 - 4 b. a programmable microprocessor-based portable unit that is separate from the
 - 5 blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video
 - 6 display for displaying information, said video display configured to display graphic and multi-line
 - 7 alphanumeric information, 2) a plurality of switches operable for interactively controlling said
 - 8 programmable microprocessor-based portable unit and for manipulating the information displayed
 - 9 on said video display, and 3) a circuit coupled to said plurality of switches for generating video
 - 10 signals in response to the operation of the switches;
 - 11 c. a digital data storage medium, the medium
 - 12 A. readable by said programmable microprocessor-based portable unit;
 - 13 and
 - 14 B. tangibly embodying therein a program of instructions executable by
 - 15 said programmable microprocessor-based portable unit, said program of instructions including
 - 16 instructions for signal processing in response to signals generated based upon said digitally encoded

17 blood glucose level signals and further for signal processing of insulin dosage data and detecting a
18 need for a change in insulin dosage;

19 d. a signal interface connected in signal communication with said programmable
20 microprocessor-based portable unit and said blood glucose monitor for coupling said digitally
21 encoded blood glucose level signals supplied by said blood glucose monitor to said programmable
22 microprocessor-based portable unit; and

23 e. signal processing means connected in signal communication with said signal
24 interface for performing signal processing functions in accordance with said program of instructions.

2. The system of claim 1, wherein said microprocessor-based portable unit is a
palm-top computer.

1 3. The system of claim 1, the blood glucose monitor for receiving a test strip
2 including a reagent impregnated portion having blood applied thereto.

1 4. The system of claim 3, the program of instructions including instructions for
2 monitoring whether a sufficient amount of blood has been applied to said reagent impregnated
3 portion of the test strip.

1 5. The system of claim 4, the program of instructions further including
2 instructions for monitoring whether said test strip is properly inserted into the monitor.

1 6. The system of claim 3, the program of instructions further including
2 instructions for monitoring whether said test strip is properly inserted into the monitor.

1 7. The system of claim 3, the program of instructions further including
2 instructions for performing a test sequence to confirm that the system is operating properly.

1 8. The system of claim 1, at least a component of said signal interface being
2 connectable with a second device, other than said blood glucose monitor, in signal communication
3 with said programmable microprocessor-based portable unit for coupling further signals supplied
4 by said second device to said programmable microprocessor-based portable unit.

1 9. The system of claim 1, wherein said programmable microprocessor-based
2 portable unit further comprises an interactive interface.

1 10. The system of claim 9, wherein said microprocessor-based interactive portable
2 unit is a palm-top computer.

1 11. The system of claim 9, the blood glucose monitor for receiving a test strip
2 including a reagent impregnated portion having blood applied thereto.

1 12. The system of claim 11, the program of instructions including instructions for
2 monitoring whether a sufficient amount of blood has been applied to said reagent impregnated
3 portion of the test strip.

1 13. The system of claim 12, the program of instructions further including
2 instructions for monitoring whether said test strip is properly inserted into the monitor.

1 14. The system of claim 11, the program of instructions further including
2 instructions for monitoring whether said test strip is properly inserted into the monitor.

1 15. The system of claim 11, the program of instructions further including
2 instructions for performing a test sequence to confirm that the system is operating properly.

1 16. The system of claim 9, at least a component of said signal interface being
2 connectable with a second device, other than said blood glucose monitor, in signal communication
3 with said programmable microprocessor-based interactive portable unit for coupling further signals
4 supplied by said second device to said programmable microprocessor-based interactive portable unit.

1 17. A method of performing diabetes self-care with a system of integrated
2 electronic devices, comprising:
3 powering a portable blood glucose monitor with one or more batteries;

receiving an amount of blood sufficient for a blood glucose monitor to run a blood glucose test sequence;

controlling the blood glucose test sequence;

computing a blood glucose level;

signal coupling the blood glucose monitor to a portable microprocessor-based

9 electronic device via a first data port, wherein said portable microprocessor-based electronic device

is separate from the blood glucose monitor and includes 1) a video display for displaying

11 information, said video display configured to display graphic and multi-line alphanumeric

12 information, 2) a plurality of switches operable for interactively controlling said portable

13 microprocessor-based electronic device and for manipulating the information displayed on said video

14 display, and 3) a circuit coupled to said plurality of switches for generating video signals in response

15 to the operation of the switches;

16 transmitting blood glucose test results from said blood glucose monitor to said
17 portable microprocessor-based electronic device.

running programs in step 2. The *run* command is used to run a program.

¹⁰ based electronic device for a second time, and in a third time, in a fourth time.

20 of insulin does not lead to a significant increase in glucose tolerance.

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34. *What is the best way to evaluate the performance of a performing band?*

1 18. The method of claim 17, the receiving including inserting a test strip into a
2 receptacle of the blood glucose monitor; and applying a drop of blood to the strip.

1 19. The method of claim 17, further comprising displaying the blood glucose level
2 on said video display.

1 20. The method of claim 17, wherein said portable, microprocessor-based
2 electronic device comprises a palm-top computer.

1 21. The method of claim 17, the receiving comprising receiving a test strip
2 including a reagent impregnated portion having blood applied thereto.

1 22. The method of claim 21, the controlling comprising monitoring whether a
2 sufficient amount of blood has been applied to said reagent impregnated portion of the test strip.

1 23. The method of claim 22, the controlling further comprising monitoring
2 whether said test strip is properly inserted into the monitor.

1 24. The method of claim 21, the controlling comprising monitoring whether said
2 test strip is properly inserted into the monitor.

1 25. The method of claim 17, the controlling comprising performing a test
2 sequence to confirm that the system is operating properly.

1 26. The method of claim 17, further comprising:
2 powering a second device;
3 signal coupling the second device to said portable microprocessor-based electronic
4 device; and
5 transmitting signals from said second device to said portable microprocessor-based
6 electronic device.

1 27. The method of claim 17, wherein said portable microprocessor-based
2 electronic device further comprises an interactive interface and said plurality of switches includes
3 a pair of spaced-apart push button switches and another pair of switches.

1 28. A blood glucose monitoring system, comprising:
2 a. a blood glucose monitor for monitoring a blood glucose level and for
3 producing digitally encoded blood glucose level signals representative of said blood glucose level;
4 b. a programmable microprocessor-based portable unit that is separate from the
5 blood glucose monitor, said programmable microprocessor-based portable unit including 1) a video
6 display for displaying information, said video display configured to display graphic and multi-line

7 alphanumeric information, 2) a plurality of switches operable for interactively controlling said
8 programmable microprocessor-based portable unit and for manipulating the information displayed
9 on said video display, and 3) a circuit coupled to said plurality of switches for generating video
10 signals in response to the operation of the switches;

11 c. digital data storage media tangibly embodying therein processor-executable
12 program instructions for signal processing in response to signals based upon said digitally encoded
13 blood glucose signals and further for signal processing of insulin dosage data and detecting a need
14 for a change in insulin dosage and further for performing a test sequence to confirm that the system
15 is operating properly;

16 d. a signal interface connected in signal communication with said programmable
17 microprocessor-based portable unit and said blood glucose monitor for coupling said digitally
18 encoded health signals supplied by said blood glucose monitor to said programmable
19 microprocessor-based portable unit; and

20 e. signal processing means connected in signal communication with said signal
21 interface for performing signal processing functions in accordance with said program of instructions.

1 29. The system of claim 28, the blood glucose monitor for receiving a test strip
2 including a reagent impregnated portion having blood applied thereto.

1 30. The system of claim 29, the program of instructions including instructions
2 further for monitoring whether a sufficient amount of blood has been applied to said reagent
3 impregnated portion of the test strip.

1 31. The system of claim 29, the program of instructions further including
2 instructions for monitoring whether said test strip is properly inserted into the monitor.

1 32. The system of claim 28, wherein said microprocessor-based portable unit is
2 a palm-top computer.

1 33. The system of claim 28, at least a component of said signal interface being
2 connectable with a second device, other than said blood glucose monitor, in signal communication
3 with said programmable microprocessor-based portable unit for coupling further signals supplied
4 by said second device to said programmable microprocessor-based portable unit.

1 34. The system of claim 28, wherein said programmable microprocessor-based
2 portable unit further comprises an interactive interface.

1 35. The system of claim 34, wherein said microprocessor-based interactive
2 portable unit is a palm-top computer.

1 36. The system of claim 34, the blood glucose monitor for receiving a test strip
2 including a reagent impregnated portion having blood applied thereto.

1 37. The system of claim 36, the program of instructions including instructions for
2 monitoring whether a sufficient amount of blood has been applied to said reagent impregnated
3 portion of the test strip.

1 38. The system of claim 36, the program of instructions further including
2 instructions for monitoring whether said test strip is properly inserted into the monitor.

1 39. The system of claim 34, at least a component of said signal interface being
2 connectable with a second device, other than said blood glucose monitor, in signal communication
3 with said programmable microprocessor-based interactive portable unit for coupling further signals
4 supplied by said second device to said programmable microprocessor-based interactive portable unit.

1 40. A system of interconnected devices for performing diabetes self-care,
2 comprising:

3 (a) a blood glucose monitor, including:
4 (i) a receptacle for receiving an amount of blood sufficient for the monitor
5 to run a blood glucose test sequence;

(ii) processing circuitry for controlling a blood glucose test sequence and computing a blood glucose level,

(iii) a battery compartment for holding a battery for powering the blood glucose monitor, and

(iv) a first data port for signal coupling to another electronic device; and

(b) a portable microprocessor-based device that is separate from the blood glucose monitor and signal coupled with the blood glucose monitor, including:

(i) a second data port for signal coupling with the first data port and receiving blood glucose test results from said blood glucose monitor,

(ii) a microprocessor that runs according to program instructions stored in a memory for performing analysis of the blood glucose test results, signal processing of insulin dosage data, and detecting a need for a change in insulin dosage,

(iii) a memory for recording the recorded blood glucose test results and insulin dosage information therein, and for containing programming for establishing a data protocol that allows digital data signal processing, and for performing analysis of blood glucose test results,

(iv) a video display for displaying information, said video display configured to display graphic and multi-line alphanumeric information,

(v) a plurality of switches operable for interactively controlling said portable microprocessor-based device and for manipulating the information displayed on said video display, and

26 (vi) a circuit coupled to said plurality of switches for generating video signals
27 in response to the operation of the switches.

1 41. The system of interconnected devices of claim 40, wherein said receptacle is
2 for receiving a test strip upon which a drop of blood is applied.

1 42. The system of interconnected devices of claim 40, the blood glucose monitor
2 further comprising a display for displaying the blood glucose level.

1 43. The system of interconnected devices of claim 40, wherein said
2 microprocessor-based portable unit is a palm-top computer.

1 44. The system of interconnected devices of claim 40, the blood glucose monitor
2 for receiving a test strip including a reagent impregnated portion having blood applied thereto.

1 45. The system of interconnected devices of claim 44, the program of instructions
2 including instructions for monitoring whether a sufficient amount of blood has been applied to said
3 reagent impregnated portion of the test strip.

1 46. The system of interconnected devices of claim 45, the program of instructions
2 further including instructions for monitoring whether said test strip is properly inserted into the
3 monitor.

1 47. The system of interconnected devices of claim 44, the program of instructions
2 further including instructions for monitoring whether said test strip is properly inserted into the
3 monitor.

1 48. The system of interconnected devices of claim 44, the program of instructions
2 further including instructions for performing a test sequence to confirm that the system is operating
3 properly.

1 49. The system of interconnected devices of claim 40, further comprising a second
2 device, other than said blood glucose monitor, comprising a third data port, said second data port of
3 said portable microprocessor-based device further for signal coupling with the third data port and
4 receiving a signal from said second device.

1 50. The system of interconnected devices of claim 40, wherein the portable
2 microprocessor-based device further comprises an interactive interface.

1 51. The system of interconnected devices of claim 50, wherein said receptacle is
2 for receiving a test strip upon which a drop of blood is applied.

1 52. The system of interconnected devices of claim 50, the blood glucose monitor
2 further comprising a display for displaying the blood glucose level.

1 53. The system of interconnected devices of claim 50, wherein said
2 microprocessor-based portable unit is a palm-top computer.

1 54. The system of interconnected devices of claim 50, the blood glucose monitor
2 for receiving a test strip including a reagent impregnated portion having blood applied thereto.

1 55. The system of interconnected devices of claim 54, the program of instructions
2 including instructions for monitoring whether a sufficient amount of blood has been applied to said
3 reagent impregnated portion of the test strip.

1 56. The system of interconnected devices of claim 55, the program of instructions
2 further including instructions for monitoring whether said test strip is properly inserted into the
3 monitor.

1 57. The system of interconnected devices of claim 54, the program of instructions
2 further including instructions for monitoring whether said test strip is properly inserted into the
3 monitor.

1 58. The system of interconnected devices of claim 54, the program of instructions
2 further including instructions for performing a test sequence to confirm that the system is operating
3 properly.

1 59. The system of claim 50, further comprising a second device, other than said
2 blood glucose monitor, comprising a third data port, said second data port of said portable
3 microprocessor-based device further for signal coupling with the third data port and receiving a
4 signal from said second device.

1 60. The system of claim 1, wherein said video display has a resolution sufficient
2 to display at least six lines of alphanumeric information, as well as allowing graphical representation
3 of statistical data.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.